Complete Summary

GUIDELINE TITLE

Evidence-based guidelines for cardiovascular disease prevention in women.

BIBLIOGRAPHIC SOURCE(S)

Mosca L, Appel LJ, Benjamin EJ, Berra K, Chandra-Strobos N, Fabunmi RP, Grady D, Haan CK, Hayes SN, Judelson DR, Keenan NL, McBride P, Oparil S, Ouyang P, Oz MC, Mendelsohn ME, Pasternak RC, Pinn VW, Robertson RM, Schenck-Gustafsson K, Sila CA, Smith SC Jr, Sopko G, Taylor AL, Walsh BW, Wenger NK, Williams CL. Evidence-based guidelines for cardiovascular disease prevention in women. Circulation 2004 Feb 10;109(5):672-93. [505 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Cardiovascular disease (CVD)

- Coronary heart disease (CHD)
- Other forms of atherosclerotic/thrombotic cardiovascular disease, such as cerebrovascular disease and peripheral arterial disease

GUIDELINE CATEGORY

Prevention
Risk Assessment

CLINICAL SPECIALTY

Cardiology
Family Practice
Internal Medicine
Nursing
Nutrition
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To present evidence-based guidelines for the prevention of cardiovascular disease (CVD) in adult women with a broad range of cardiovascular risk

TARGET POPULATION

Adult women 20 years and older with a broad range of cardiovascular risk

INTERVENTIONS AND PRACTICES CONSIDERED

1. Assessment and stratification of risk
2. Lifestyle interventions
    - Avoidance of cigarette smoking and exposure to environmental tobacco
    - Physical activity and exercise
    - Cardiac rehabilitation
    - Heart-healthy diet
    - Weight maintenance/reduction through diet, exercise, and behavioral programs
    - Psychosocial factors (evaluation and treatment for depression when indicated)
    - Omega 3 fatty acid supplementation
    - Folic acid supplementation
3. Major risk factor interventions
    - Management of blood pressure through lifestyle approaches (weight management, diet, activity, moderation of alcohol) and drugs, such as thiazide diuretics

- Management of lipids through lifestyle, diet therapy, and pharmacotherapy (low-density lipoprotein cholesterol [LDL-C]–lowering therapy (statin), niacin or fibrate)
- Management of diabetes (glycemic control) with lifestyle and pharmacotherapy

4. Preventive drug interventions
    - Antiplatelet therapy (aspirin, tr clopidogrel, or other antiplatelet)
    - Beta-blockers (carvedilol, propranolol, acebutolol, bisoprolol, atenolol, metoprolol [Lopressor], sotalol, practolol, timolol)
    - Angiotensin-converting enzyme (ACE) inhibitors (ramipril, zofenopril, fosinopril, captopril, perindopril, lisinopril, trandolapril, quinapril, enalapril)
    - Angiotensin-receptor blockers (ARBs) (losartan, valsartan)
5. Atrial fibrillation/stroke prevention measures (warfarin, aspirin)

*Guideline developers considered but recommended against the following interventions for prevention of cardiovascular disease: hormone therapy in postmenopausal women, antioxidant supplements in general populations of women, and routine use of aspirin in women at low risk for cardiovascular disease

MAJOR OUTCOMES CONSIDERED

- Framingham Point Score Estimates of 10-year risk for coronary heart disease (CHD) in women, based on age, total cholesterol, smoking status, high-density lipoprotein (HDL) levels, systolic blood pressure
- Major cardiovascular disease (CVD) clinical end points (death, myocardial infarction, stroke, revascularization procedure, congestive heart failure, or a composite cardiovascular disease end point)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Selection of Topics and Candidate Recommendations

The Expert Panel reviewed previously published American Heart Association (AHA) recommendations for the primary and secondary prevention of cardiovascular disease (CVD) and discussed and debated topics that were timely, with the goal of develping a set of candidate recommendations for searching and rating. A list of preselected recommendations was circulated to the panel, and experts were asked to independently rate the priority of the recommendation and suggest modifications to the wording. Recommendations were then selected for the systematic literature search.

Inclusion and exclusion criteria for studies to be evaluated as part of the evidence-rating process were established according to the Expert Panel recommendation to focus on major CVD clinical end points (death, myocardial

infarction, stroke, revascularization procedure, congestive heart failure, or a composite CVD end point) in high-quality studies. The importance of other outcomes, such as quality of life and resource utilization, was recognized, but these were not feasible to include in this version.

The purpose of the clinical recommendations is to provide guidance with regard to risk-reducing interventions; therefore, the panel supported the inclusion of studies that were interventional rather than etiologic in nature. For example, studies of the impact of weight loss on major clinical CVD outcomes were included but not studies that simply related obesity to CVD. Inclusion criteria were randomized clinical trials or large prospective cohort studies (>1,000 subjects) with CVD risk–reducing interventions evaluated. Also, meta-analyses that used a quantitative systematic review process were included. All studies had to have at least 10 cases of major clinical CVD end points reported. Studies with surrogate end points were excluded unless they met the minimum number of outcome events. Studies meeting the above criteria were included whether or not there were female participants.

The systematic search was conducted by the Duke Center for Clinical Health Policy Research, Durham, NC. Search terms were constructed for each clinical recommendation, with an "explode" term to include related articles. Three databases were searched electronically on OVID, including Medline (1966 through July 3, 2003), the Cumulative Index to Nursing & Allied Health (CINAHL) (1982 through July 3, 2003), and PsycInfo (1872 through July 3, 2003). More than 99% of the studies were located in Medline. Nearly 7,000 titles and abstracts identified through the systematic search were reviewed to exclude those that did not meet obvious eligibility criteria or were not available in English. More than 1,200 articles were obtained for full-text screening and reviewed for inclusion/exclusion criteria. A standardized abstraction form was completed to document the study design, end points, and decision to include or exclude.

NUMBER OF SOURCE DOCUMENTS

399 total articles were included for evidence tables:

Hyperlipidemia – 40
Physical activity – 52
Tobacco use – 16
Antiplatelet therapy – 31
Blood pressure management – 31
Beta-blocker therapy – 30
Cardiac rehabilitation – 19
Angiotensin-converting enzyme inhibitor (ACE)/angiotensin-receptor blockers therapy – 21
Weight management – 6
Diabetes – 8
Hormone replacement therapy – 41
Diet modification – 68
Warfarin in atrial fibrillation – 11
Aspirin for primary prevention – 10
Depression therapy – 2
Antioxidant supplementation – 16

Omega-3 fatty acid supplementation – 8
Folic acid supplementation – 3

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level of Evidence

A: Sufficient evidence from multiple randomized trials
B: Limited evidence from single randomized trial or other nonrandomized studies
C: Based on expert opinion, case studies, or standard of care

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Included articles were abstracted for more detailed information on a standardized form that included study type, number of participants (% female) at baseline, population characteristics (primary prevention, secondary prevention, or mixed), mean age (age range), percentage diabetic, percentage white, intervention(s) (for drug trials, information was listed about dose, schedule, and duration), primary outcomes including numbers of events, subgroup analysis of clinical end points in women (if analysis available), and comments about important methodological or quality issues.

Expert Panel members reviewed the summary evidence tables for completeness. Tables were updated with publications that were inadvertently omitted or included during the systematic search to comprise the final evidence tables. In addition, results of trials or meta-analyses published subsequent to the systematic search that met inclusion criteria were made available to the Expert Panel. A complete listing of references reviewed by the Expert Panel and used to compile the evidence summary tables is listed in Appendix II of the original guideline document. The evidence summary tables are located in an online-only Data Supplement at http://www.circulationaha.org.

Evidence Rating System

Two primary reviewers from the Expert Panel were assigned to each candidate recommendation to propose an initial evidence rating and suggest modifications to wording on the basis of the results of the systematic evidence search. A series of conference calls was held to discuss the rating and revised wording of recommendations. Each expert received a final copy of the evidence tables and voted independently on the strength of the recommendation and level of evidence. The experts also evaluated the likelihood that data from men would

generalize to women with regard to each specific risk-reducing intervention. Criteria to determine generalizability were based on factors such as differences in the epidemiology and pathophysiology of cardiovascular disease between men and women (e.g., the ratio of hemorrhagic stroke to coronary events may alter the risk-to-benefit ratio of aspirin in primary prevention for women versus men). The final rating of evidence was determined by a majority vote.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Clinical Recommendations

Each recommendation in the guideline is accompanied by the strength of recommendation, level of evidence to support it, and the generalizability index. The strength of the recommendation is based on not only the level of evidence to support a clinical recommendation, but also on factors such as feasibility of conducting randomized controlled trials in women. Recommendations are grouped in the following categories: lifestyle interventions; major risk factor interventions; atrial fibrillation/stroke prevention; preventive drug interventions; and a Class III category, where routine intervention for cardiovascular disease prevention is not recommended.

Several lifestyle interventions were rated as Class I recommendations, although the supporting evidence was in many cases classified as level B. These decisions reflect the availability of observational studies as evidence to support the recommendation, as well as ethical issues that preclude conducting randomized controlled trials of certain lifestyle interventions. For example, the Expert Panel regarded smoking cessation as a top priority in clinical practice and suggested that the absence of trial data should not preclude a strong emphasis on clinician interventions to help women stop smoking. More detailed information on how to treat tobacco dependence is available at http://www.surgeongeneral.gov/tobacco/treating_tobacco_use.pdf.

Lifestyle interventions received Class I recommendations from the panel not only because of their potential to reduce clinical cardiovascular disease (CVD), but also because heart-healthy lifestyles may prevent the development of major risk factors for CVD. Prevention of the development of risk factors through a positive lifestyle approach may minimize the need for more intensive intervention in the future.

Although evidence to support a clinical benefit for CVD event reduction was limited with some interventions (e.g., treatment of depression), there may be other important benefits associated with these therapies that are reflected in the strength of the recommendation, such as improved quality of life. Behavioral interventions may have benefits that are not captured by the panel´s stringent outcome criteria for clinical CVD events. Weight management via lifestyle and behavioral approaches was rated as a Class I recommendation, level B. The panel

suggested there was insufficient evidence to rate more aggressive medical and surgical approaches that generally are limited to a small subset of women.

The panel´s dietary recommendations emphasize intake of a variety of heart-healthy foods. The panel concluded that intake of fish has been associated with a reduced risk of CVD. The benefits of fish seem to result, at least in part, from omega-3 fatty acids. Nonetheless, women of childbearing age, especially pregnant women, should avoid shark, swordfish, king mackerel, and tilefish because the relatively high content of mercury in these fish may impair fetal neurological development. Still, these women can eat other kinds of fish, such as catfish, flounder, and salmon, which have less mercury. For a more complete listing of mercury levels in different types of fish, see the US Food and Drug Administration Web site at http://www.cfsan.fda.gov/~frf/sea-mehg.html. Women who do not eat fish might consider nonmarine sources of omega-3 fatty acids, such as flaxseed oil, walnut oil, canola oil, soybean oil, or walnuts. However, there is less evidence supporting a cardiovascular benefit from these sources of omega-3 fatty acids.

Other expert panels and organizations (including the National Cholesterol Education Program Adult Treatment Panel III [NCEP ATP III]; the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure [JNC 7], and the American Diabetes Association) have addressed control of major risk factors extensively and can be referred to for more specific information about management approaches. For example, the panel´s recommendation to encourage an optimal blood pressure through lifestyle approaches should be implemented using more detailed information from the JNC 7 report about weight management, adopting a Dietary Approaches to Stop Hypertension (DASH) eating plan, dietary sodium reduction, physical activity, and moderation of alcohol consumption. Similarly, NCEP ATP III provides algorithms for cholesterol management and is updated as new evidence becomes available. According to NCEP/ATP III, low density lipoprotein (LDL) cholesterol is the primary target of lipid-lowering therapy, and intensity of therapy should be matched to the absolute risk of the patient. Glycemic control received a Class I recommendation from the Expert Panel. Treatment of hyperglycemia has been shown to reduce or delay complications of diabetes such as retinopathy, nephropathy, and neuropathy, which underscores the importance of glycemic control in diabetic patients. Moreover, both lifestyle intervention and (to a lesser degree) metformin therapy have been shown to reduce the incidence of diabetes.

Although there was good consensus on the use of aspirin (75 to 162 mg) in high-risk women, recommendations for aspirin therapy in intermediate- and lower-risk women were more challenging. The difficulty in developing these recommendations was due to the lack of data from primary prevention trials that included women and the possibility that data on men may not necessarily be extrapolated to women. Uncontrolled hypertension is not uncommon in women, and aspirin therapy may increase the risk of hemorrhagic stroke in this setting. Moreover, the risk of gastrointestinal bleeding and other side effects may outweigh the potential benefits of aspirin in women at lower risk for CVD. The panel suggested a conservative approach, pending the results of ongoing clinical trials. It was also noted that nonsteroidal anti-inflammatory medications should not be substituted for aspirin for CVD prevention. For stroke prevention among women with atrial fibrillation, a dose of 325 mg of aspirin is needed if there is a

contraindication to warfarin therapy or if the risk of a stroke is considered low (<1% annual event rate per year). Tools to determine stroke risk are available at http://www.nhlbi.nih.gov/about/framingham/stroke.htm.

The Class III recommendations on hormone therapy and antioxidant supplementation were based on recent clinical trials showing no benefit for CVD prevention and possible adverse effects of these interventions. The panel acknowledged that major trials have been limited to specific types and dosages of these agents, and those results may not generalize to compounds not tested in clinical studies. In particular, ongoing trials will give more information about unopposed estrogen therapy and clinical outcomes. However, given the unproven benefit and possible harm associated with postmenopausal hormone therapies, it was suggested that a conservative approach be taken in clinical practice unless further research is available to support use for CVD prevention. The use of hormone therapy for menopausal symptoms has been addressed by other professional societies. Although hormone therapy is not recommended for CVD prevention, women and their healthcare providers should weigh the potential risks of therapy against the potential benefits for menopausal symptom control.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Class I: Intervention is useful and effective.
Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.
Class IIb: Usefulness/efficacy is less well established by evidence/opinion.
Class III: Intervention is not useful/effective and may be harmful.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The American Heart Association Science Advisory and Coordinating Committee approved these guidelines on December 1, 2003.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Each recommendation is rated based on the level of the evidence, the strength of the recommendation, and the generalizability index. Definitions of the strengths of the recommendations (I, IIa, IIb, III), levels of the evidence (Levels A, B, C), and generalizability index (1, 2, 3, 0) are presented at the end of the "Major Recommendations" field.

Lifestyle Interventions

Cigarette smoking
Consistently encourage women not to smoke and to avoid environmental tobacco. (Class I, Level B) Generalizable index (GI) =1

Physical activity
Consistently encourage women to accumulate a minimum of 30 minutes of moderate-intensity physical activity (e.g., brisk walking) on most, and preferably all, days of the week. (Class I, Level B) GI =1

Cardiac rehabilitation
Women with a recent acute coronary syndrome or coronary intervention, new-onset or chronic angina should participate in a comprehensive risk-reduction regimen, such as cardiac rehabilitation or a physician-guided home- or community-based program. (Class I, Level B) GI =2

Heart-healthy diet
Consistently encourage an overall healthy eating pattern that includes intake of a variety of fruits, vegetables, grains, low-fat or nonfat dairy products, fish, legumes, and sources of protein low in saturated fat (e.g., poultry, lean meats, plant sources).

Limit saturated fat intake to <10% of calories, limit cholesterol intake to <300 mg/d, and limit intake of trans fatty acids. (Class I, Level B) GI =1

Weight maintenance/reduction
Consistently encourage weight maintenance/reduction through an appropriate balance of physical activity, caloric intake, and formal behavioral programs when indicated to maintain/achieve a body mass index (BMI) between 18.5 and 24.9 kg/m^2 and a waist circumference <35 in. (Class I, Level B) GI =1

Psychosocial factors
Women with cardiovascular disease (CVD) should be evaluated for depression and refer/treat when indicated. (Class IIa, Level B) GI =2

Omega 3 fatty acids
As an adjunct to diet, omega 3 fatty-acid supplementation may be considered in high-risk* women. (Class IIb, Level B) GI =2

Folic acid
As an adjunct to diet, folic acid supplementation may be considered in high-risk* women (except after revascularization procedure) if a higher-than-normal level of homocysteine has been detected. (Class IIb, Level B) GI =2

Major Risk Factor Interventions

Blood pressure—lifestyle
Encourage an optimal blood pressure of <120/80 mm Hg through lifestyle approaches. (Class I, Level B) GI =1

Blood pressure—drugs
Pharmacotherapy is indicated when blood pressure is ≥140/90 mm Hg or an even lower blood pressure in the setting of blood pressure–related target-organ damage or diabetes. Thiazide diuretics should be part of the drug regimen for most patients unless contraindicated. (Class I, Level A) GI =1

Lipid, lipoproteins
Optimal levels of lipids and lipoproteins in women are low-density lipoprotein cholesterol (LDL-C) <100 mg/dL, high-density lipoprotein cholesterol (HDL-C) >50 mg/dL, triglycerides <150 mg/dL, and non–HDL-C (total cholesterol minus HDL cholesterol) <130 mg/dL and should be encouraged through lifestyle approaches. (Class I, Level B) GI =1

Lipids—diet therapy
In high-risk* women or when LDL-C is elevated, saturated fat intake should be reduced to <7% of calories and cholesterol to <200 mg/d, and trans fatty acid intake should be reduced. (Class I, Level B) GI =1

Lipids—pharmacotherapy—high risk*
Initiate LDL-C–lowering therapy (preferably a statin) simultaneously with lifestyle therapy in high-risk women with LDL-C ≥100 mg/dL (Class I, Level A) GI = 1, and initiate statin therapy in high-risk women with an LDL-C <100 mg/dL unless contraindicated (Class I, Level B) GI =1

Initiate niacin** or fibrate therapy when HDL-C is low, or non–HDL-C elevated in high-risk women. (Class I, Level B) GI =1

Lipids—pharmacotherapy—intermediate risk***
Initiate LDL-C–lowering therapy (preferably a statin) if LDL-C level is ≥130 mg/dL on lifestyle therapy (Class I, Level A) GI = 1, or niacin** or fibrate therapy when HDL-C is low or non–HDL-C elevated after LDL-C goal is reached. (Class I, Level B) GI =1

Lipids—pharmacotherapy—lower risk****
Consider LDL-C–lowering therapy in low-risk women with 0 or 1 risk factor when LDL-C level is ≥190 mg/dL or if multiple risk factors are present when LDL-C is ≥160 mg/dL (Class IIa, Level B) or niacin** or fibrate therapy when HDL-C is low or non–HDL-C elevated after LDL-C goal is reached. (Class IIa, Level B) GI =1

Diabetes
Lifestyle and pharmacotherapy should be used to achieve near normal glycosylated hemoglobin (HbA1C) (<7%) in women with diabetes. (Class I, Level B) GI =1

Preventive Drug Interventions

Aspirin—high risk*
Aspirin therapy (75 to 162 mg), or clopidogrel if patient is intolerant to aspirin, should be used in high-risk women unless contraindicated. (Class I, Level A) GI =1

Aspirin—intermediate risk***
Consider aspirin therapy (75 to 162 mg) in intermediate-risk women as long as blood pressure is controlled and benefit is likely to outweigh risk of gastrointestinal side effects. (Class IIa, Level B) GI =2

Beta-Blockers
Beta-blockers should be used indefinitely in all women who have had a myocardial infarction or who have chronic ischemic syndromes unless contraindicated. (Class I, Level A) GI =1

Angiotensin-converting enzyme (ACE) inhibitors
ACE inhibitors should be used (unless contraindicated) in high-risk* women. (Class I, Level A) GI =1

Angiotensin-receptor blockers (ARBs)
ARBs should be used in high-risk* women with clinical evidence of heart failure or an ejection fraction <40% who are intolerant to ACE inhibitors. (Class I, Level B) GI =1

Atrial Fibrillation/Stroke Prevention

Warfarin—atrial fibrillation
Among women with chronic or paroxysmal atrial fibrillation, warfarin should be used to maintain the international normalized ratio (INR) at 2.0 to 3.0 unless they are considered to be at low risk for stroke (<1%/year) or high risk of bleeding. (Class I, Level A) GI =1

Aspirin—atrial fibrillation
Aspirin (325 mg) should be used in women with chronic or paroxysmal atrial fibrillation with a contraindication to warfarin or at low risk for stroke (<1%/year). (Class I, Level A) GI =1

Class III Interventions

Hormone therapy
Combined estrogen plus progestin hormone therapy should not be initiated to prevent CVD in postmenopausal women. (Class III, Level A)

Combined estrogen plus progestin hormone therapy should not be continued to prevent CVD in postmenopausal women. (Class III, Level C)

Other forms of menopausal hormone therapy (e.g., unopposed estrogen) should not be initiated or continued to prevent CVD in postmenopausal women pending the results of ongoing trials. (Class III, Level C)

Antioxidant supplements
Antioxidant vitamin supplements should not be used to prevent CVD pending the results of ongoing trials. (Class III, Level A) GI =1

Aspirin—lower risk****
Routine use of aspirin in lower-risk women is not recommended pending the results of ongoing trials. (Class III, Level B) GI =2

*High risk is defined as coronary heart disease (CHD) or risk equivalent, or 10-year absolute CHD risk >20%.
**Dietary supplement niacin must not be used as a substitute for prescription niacin, and over-the-counter niacin should only be used if approved and monitored by a physician.
*** Intermediate risk is defined as 10-year absolute CHD risk 10% to 20%.
****Lower risk is defined as 10-year absolute CHD risk <10%.

Definitions:

Strength of Recommendations

Classification:

Class I: Intervention is useful and effective.
Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.
Class IIb: Usefulness/efficacy is less well established by evidence/opinion.
Class III: Intervention is not useful/effective and may be harmful.

Level of Evidence

A: Sufficient evidence from multiple randomized trials
B: Limited evidence from single randomized trial or other nonrandomized studies
C: Based on expert opinion, case studies, or standard of care

Generalizability Index

1: Very likely that results generalize to women
2: Somewhat likely that results generalize to women
3: Unlikely that results generalize to women
0: Unable to project whether results generalize to women

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- The recommendations may assist healthcare providers in optimizing cardiovascular (CVD) preventive care for all women age 20 years and older.
- Primary prevention interventions have the potential to reduce the development of risk factors for CVD.
- Secondary prevention interventions have the potential for reducing morbidity and mortality related to established CVD.

POTENTIAL HARMS

- Side effects of medication. For example, aspirin may increase the risk of hemorrhagic stroke and gastrointestinal bleeding.
- Side effects of mercury exposure from eating certain types of fish

CONTRAINDICATIONS

CONTRAINDICATIONS

Although fish has been associated with a reduced risk of cardiovascular disease (CVD), women of childbearing age, especially pregnant women, should avoid shark, swordfish, king mackerel, and tilefish because the relatively high content of mercury in these fish may impair fetal neurological development.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Implementation of these guidelines may differ among countries and regions for cultural, medical, and economic reasons. In addition, application of these guidelines should also take into consideration individual factors such as frailty and life expectancy.

Although evidence to support a clinical benefit for cardiovascular disease (CVD) event reduction was limited with some interventions (e.g., treatment of depression), there may be other important benefits associated with these therapies that are reflected in the strength of the recommendation, such as improved quality of life. Behavioral interventions may have benefits that are not captured by the panel´s stringent outcome criteria for clinical cardiovascular disease events. Weight management via lifestyle and behavioral approaches was rated as a Class I recommendation, level B. The panel suggested there was insufficient evidence to rate more aggressive medical and surgical approaches that generally are limited to a small subset of women.

Limitations

The process of developing clinical guidelines has several limitations, even when a systematic approach is undertaken. Most importantly, data used to establish recommendations might be generated from populations that do not reflect the characteristics of the patient being treated, and individual responses can vary significantly. The clinical cardiovascular end points chosen for inclusion in the systematic evaluation do not necessarily reflect the net clinical impact and do not

include many end points that are clinically important but often not reported (e.g., symptoms, quality of life, functional status, hospitalizations, resource utilization). The guideline panel simplified the recommendation for each level of risk for purposes of clinical utility and acknowledge that there might be variability in efficacy and effectiveness of various interventions within the same risk intervention category (e.g., various doses or types of physical activity or drugs within the same class may yield different results). The Framingham risk score may not apply equally to all populations, but it performs well within subgroups. Guideline developers may have omitted or included some studies because of the limitations of electronic searching and human error; however, the likelihood that such an inadvertent omission or inclusion would alter a recommendation is small. Recommendations are based on evidence available to the panel through November 2003, and as science evolves, recommendations may have to be revised. Finally, guideline developers do not include a comprehensive plan for implementation of the guidelines in this document. The American Heart Association (AHA) is developing professional education programs and other initiatives to facilitate the dissemination and implementation of the guidelines.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Mosca L, Appel LJ, Benjamin EJ, Berra K, Chandra-Strobos N, Fabunmi RP, Grady D, Haan CK, Hayes SN, Judelson DR, Keenan NL, McBride P, Oparil S, Ouyang P, Oz MC, Mendelsohn ME, Pasternak RC, Pinn VW, Robertson RM, Schenck-Gustafsson K, Sila CA, Smith SC Jr, Sopko G, Taylor AL, Walsh BW, Wenger NK, Williams CL. Evidence-based guidelines for cardiovascular disease prevention in women. Circulation 2004 Feb 10;109(5):672-93. [505 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Feb

GUIDELINE DEVELOPER(S)

American College of Cardiology Foundation - Medical Specialty Society
American College of Nurse Practitioners - Medical Specialty Society
American College of Obstetricians and Gynecologists - Medical Specialty Society
American College of Physicians - Medical Specialty Society
American Heart Association - Professional Association
American Medical Women's Association
Association of Black Cardiologists - Medical Specialty Society
Centers for Disease Control and Prevention - Federal Government Agency [U.S.]
National Heart, Lung, and Blood Institute (U.S.) - Federal Government Agency [U.S.]
Office of Research on Women's Health (NIH) - Federal Government Agency [U.S.]
Society of Thoracic Surgeons
World Heart Federation - Medical Specialty Society

SOURCE(S) OF FUNDING

American Heart Association and the Foundation for the Advancement of Cardiac Therapies (FACT) Foundation, Palm Beach, FL

GUIDELINE COMMITTEE

Expert Panel/Writing Group for Cardiovascular Disease Prevention in Women

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Expert Panel/Writing Group Members: Lori Mosca, MD, PhD, American Heart Association (AHA) (Chair); Lawrence J. Appel, MD, AHA; Emelia J. Benjamin, MD, AHA; Kathy Berra, MSN, ANP, AHA, American College of Nurse Practitioners; Nisha Chandra-Strobos, MD, AHA; Rosalind P. Fabunmi, PhD, AHA; Deborah Grady, MD, MPH, American College of Physicians; Constance K. Haan, MD, Society of Thoracic Surgeons; Sharonne N. Hayes, MD, American College of Cardiology; Debra R. Judelson, MD, American Medical Women´s Association; Nora L. Keenan, PhD, Centers for Disease Control and Prevention; Patrick McBride, MD, MPH, AHA; Suzanne Oparil, MD, AHA; Pamela Ouyang, MD, AHA; Mehmet C. Oz, MD, AHA; Michael E. Mendelsohn, MD, AHA; Richard C. Pasternak, MD, AHA; Vivian W. Pinn, MD, Office of Research on Women´s Health; Rose Marie Robertson, MD, AHA; Karin Schenck-Gustafsson, MD, PhD, AHA; Cathy A. Sila, MD, AHA; Sidney C. Smith, Jr, MD, World Heart Federation; George Sopko, MD, MPH, National Heart, Lung and Blood Institute; Anne L. Taylor, MD, Association of Black Cardiologists; Brian W. Walsh, MD, American College of Obstetricians and Gynecologists; Nanette K. Wenger, MD, AHA; Christine L. Williams, MD, MPH, AHA

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

ENDORSER(S)

American Academy of Physician Assistants - Professional Association
American Association for Clinical Chemistry, Inc.
American Association of Cardiovascular and Pulmonary Rehabilitation - Medical Specialty Society
American Diabetes Association - Professional Association
American Geriatrics Society - Medical Specialty Society
American Society for Preventive Cardiology - Medical Specialty Society
American Society of Echocardiography - Professional Association
American Society of Nuclear Cardiology - Professional Association
Association of Women's Health, Obstetric, and Neonatal Nurses - Professional Association
Black Women's Health Imperative - Private Nonprofit Organization
Canadian Women's Health Network - Professional Association
Jacobs Institute for Women's Health - Private Nonprofit Organization
National Women's Health Network - Private Nonprofit Organization
Partnership for Gender-Specific Medicine - Professional Association
Preventive Cardiovascular Nurses Association - Medical Specialty Society
Sister to Sister: Everyone Has a Heart Foundation, Inc. - Professional Association
Society for Women's Health Research - Private Nonprofit Research Organization
Society of Geriatric Cardiology - Professional Association
The Mended Hearts Inc. - Private Nonprofit Organization
The North American Menopause Society - Private Nonprofit Organization
Women's Health Research Center - Professional Association
WomenHeart the National Coalition for Women with Heart Disease - Private Nonprofit Organization

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Heart Association Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from the American Heart Association, Public Information, 7272 Greenville Ave, Dallas, TX 75231-4596; Phone: 800-242-8721

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Evidence-Based Guidelines for Cardiovascular Disease Prevention in Women: Evidence Summary Tables. 2004.

Electronic copies: Available from the American Heart Association Web site.

Print copies: Available from the American Heart Association, Public Information, 7272 Greenville Ave, Dallas, TX 75231-4596; Phone: 800-242-8721

PATIENT RESOURCES

The following are available:

- Cardiology Patient Page. Heart Disease Prevention in Women. 2004.

  Electronic copies: Available from the Circulation Web site.

- AHA Special Report: Women and Heart Disease. 2004.

  Electronic copies: Available from the American Heart Association (AHA) Web site.

- Patient Information Poster. 2004

  Electronic copies: Available in Portable Document Format (PDF) from the American Heart Association (AHA) Web site.

The following brochures are also available:

- Go red for women
- How do you go red?
- What is go red for women?

Additional healthcare provider tools for using the women´s guidelines in practice are also available from the AHA Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on May 6, 2004. The information was verified by the guideline developer on June 4, 2004.

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